REMARKS

Please reconsider this application in view of the above amendments and the following remarks.

- Claims 40-48, 50-63, 78-81, 85-88, and 100-101 are pending.
- Claims 40-48, 50-63, 78-81, 85-88, and 100-101 are rejected.
- Claims 64-77, 82-84, and 89-99 are canceled.

Applicant has removed from the specification the material that the Examiner has deemed new matter. As discussed below, this amendment was in response to the Examiner's acknowledgement that the "formal addition of [these] specification paragraphs . . . is not required to show these teachings".

Paragraph 1

The Examiner references 37 CFR 1.144 to support that a "complete reply to the final rejection must include cancellation of nonelected claims. . . ". 37 CFR 1.144 deals with when a petition seeking review of a restriction requirement must be made, not with when withdrawn claims must be deleted from an application. Nonetheless, to expedite issuance of the case, Applicant has canceled the withdrawn claims without prejudice to its right to incorporate those claims into another application.

Applicant believes that the Examiner mistakenly included Claim 63 in the discussion of this paragraph. If the Examiner intended to include Claim 63 in the discussion, Applicant requests that Claim 63 be rejoined into the application because it contains each and every limitation of allowable claim 60.

Paragraph 2 and 3

Applicant notes that the MPEP has not been subjected to or adopted using the rulemaking procedures of the Administrative Procedure Act. Therefore, while binding on the patent office, the MPEP is not binding on the public or on Applicant. Applicant has

reviewed the rules in the Code of Federal Regulations, Title 37, and finds no requirement that the addition of material incorporated by reference must consist of an exact duplicate of the "actual text". If Applicant has overlooked the appropriate rule, please point it out.

MPEP 608.01 says that incorporation by reference is allowed, but it does not mandate that the "actual text" of the incorporated material be used.

Likewise with MPEP 2163.07(b), it say, "[r]eplacing the identified material incorporated by reference with the actual text is NOT new matter". It does not say that failing to use the actual text of the incorporated material IS new matter.

Moreover, MPEP 2163.07(b) also says "[t]he information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed". And MPEP 2163.07 (I) says, "mere rephrasing of a passage does not constitute new matter". Therefore, even if using the "actual text" was required, that actual text qualifies for rephrasing to the same extent as any other part of the application as filed.

Nonetheless, since the Examiner believes the formal inclusion of the text is not necessary to support a teaching of an "aromatic quaternary ammonium" ion, Applicant has removed the amendments to the specification to facilitate issuance of the patent.

The Examiner implies that Applicant has mischaracterized the material of the incorporated references and cites several examples of such characterizations.

The 5,069,899 reference teaches benzalkonium, cetypyrridinium, and benzyl dimethyl stearyl ammonium at column 2, line 54. One of ordinary skill in the art recognizes that these are all aromatic ammonium ions regardless of whether the Patentee in 5,069,899 so characterized them. Moreover, nowhere does this reference state or imply that chlorides are required, contrary to the Examiner's contention that the reference "specifically requires benzalkonium chloride".

With respect to reference 3,844,989, within which the Examiner is unable to find a reference to "aromatic", a class of "alkyl aryl" ions, or a chemical with vinyl pyridine

and benzyl, these are all explicitly in the document regardless of whether the Examiner can find them. All aryl groups are aromatic. The 989-patent teaches a number of aryl-group-containing compounds, which is the same as teaching an "aromatic" genus. Table I, example 10 uses 4-vinylpyridine benzyl chloride, which is a chemical with vinyl pyridine and benzyl. Finally, the formula at the top of Column 2 teaches many ions some of which have alkyls and aryls.

Paragraph 6

35 USC § 112

The Examiner has stated that some material in claims 100 and 101 is new matter, but has failed to identify which material is new matter. This leaves Applicant guessing at what the actual 112 rejection of these claims is. Please clarify the rejection or remove it.

As far as the recitation of specific quaternary ammonium ions in the claims, the list is a compilation of all or essentially all quaternary ammonium ions listed in the application as filed including quaternary ions disclosed in the material that was incorporated into this application by reference. Therefore, that listing at least is not new matter.

Paragraph 7

Claims 60-62, 50-51, and 78-80 are rejected under 35 USC § 102(b) as being anticipated by Onishi et al. (5,670,558).

Claim 60 recites, "the step of applying comprises providing a solution comprising at least one therapeutic drug and the adhesion enhancer". Onishi fails to teach an adhesion enhancer. To the extent that the Examiner equates EVAL with an adhesion enhancer, the Examiner has cited no art showing that EVAL is an adhesion enhancer; the Examiner relies on Applicant's teachings for that element. To the extent that some of Applicant's species combine a drug and EVAL, Onishi does not teach applying a solution containing a drug and EVAL.

With respect to claim 78, it claims coating a surface with a formulation containing an adhesion enhancer and the heparin-containing compound. Onishi fails to teach an adhesion enhancer. To the extent that the Examiner equates EVAL with an adhesion enhancer, the Examiner has cited no art showing that EVAL is an adhesion enhancer; the Examiner relies on Applicant's teachings for that element. To the extent that some of Applicant's species combine heparin-containing compounds and EVAL, Onishi does not teach applying a solution containing a heparin-containing compound and EVAL.

Onishi teaches a polymer solution containing an antithrombotic agent and a polymer capable of forming a surface lubricating layer. This polymer is identified exclusive of EVAL and the list of polymers that contains EVAL. The Examiner must show that the prior art or Onishi demonstrates the equivalence of Onishi's first polymer with the adhesion enhancer of Applicant before an anticipation-based rejection is appropriate. Onishi directly teaches the inequivalence of its two polymer types in Onishi's system. Why would one of ordinary skill in the art expect the two polymer types to be equivalent in Applicant's system? The two polymer types are not inherently equivalent and the prior art of record neither teaches them as equivalent nor implies their equivalence. Therefore, this rejection cannot stand. Please remove it.

Since Onishi does not teach each and every element of the claims, it does not anticipate the claims. Therefore, please remove this rejection of claims 60 and 78.

Claims that depend from claims 60 and 78 -- 61, 62, 50-51, and 79-80 -- are patentable for at least the same reasons as Claims 60 and 78. Therefore, Applicant need not explain how the limitations added by the dependent claims further distinguish these claims from Onishi. But Applicants do not acquiesce to the Examiner's position with respect to the additional limitations and reserve the right to deal with the specifics of those further limitations in the future, if that becomes necessary.

Paragraph 8

The Examiner has rejected claims 60-62 and 78 under 35 USC § 102(e) as being anticipated by Goicoechea.

Goicoechea fails to teach a solution of a drug and an adhesion enhancer. Claims 60-62 and 78 each require a drug and an adhesion enhancer.

The Examiner cites column 4, line 45, and column 5, lines 5-11 as supporting that Goicoechea teaches a solution of polymer and heparin. Goicoechea teaches applying the polymeric material solution to a stent. Column 4, line 45. The solution is then dried to form a coating. Goicoechea then teaches that that coating may also incorporate certain drugs such as heparin. Column 5, line 4. This disclosure fails to teach that the drug and the polymer are both part of the same application solution.

The Examiner's arguments concerning the juxtaposition of the discussion of the radiopaque material and the therapeutic agent are inapposite. The radioopaque salts are many times less temperature sensitive and therefore, many times more suitable for the heat processing described for forming the polymeric skin of Goicoechea than are the drugs described by Goicoechea.

The Examiner's argument is this: because of how the paragraph describing the radiopaque material processing and the paragraph containing the drug description are arranged, the specification teaches applying the drug and the polymer in the same application solution. Certainly, Goicoechea is silent about whether the drug is applied in the same solution as is the polymer. If the feature is not explicitly present, it must be inherent to find anticipation. The drug of Goicoechea need not be applied as part of the polymer solution. Therefore, Goicoechea neither explicitly nor inherently teaches a polymer solution containing a drug and the polymer. Anticipation is not the correct standard for using Goicoechea as prior art to reject these claims.

Goicoechea uses a polymer skin or coating to "totally isolate[d] from the blood vessel wall and the blood stream". Goicoechea does not use its polymer skin as an adhesion enhancer, nor does it teach that its skin enhances adhesion in any way. One of ordinary skill would not recognize that Goicoechea's skin improves the connection of drugs to the surface of the stent. In fact, the only way to start with Goicoechea and arrive at Applicant's invention is to use Applicant's disclosure as a road map. For the Examiner to equate the polymer skin with an adhesion enhancer, she must be relying on facts external

to the record because using a polymer coating does not inherently improve the adhesion between a drug and a stent. Some choices of polymer will degrade adhesion. Please identify those external facts and appropriately frame this rejection as an obviousness rejection or remove it.

Claims 61 and 62 have limitations in addition to requiring a solution with a drug and an adhesion enhancer. Because these claims are patentable for the same reason as their parent claim, Applicant need not explain how the limitations added by the dependent claims further distinguish these claims from these cited teachings. But Applicants do not acquiesce to the Examiner's position with respect to the additional limitations and reserve the right to deal with the specifics of those further limitations in the future, if that becomes necessary.

Paragraph 9

The Examiner has rejected claims 58-59, 48, and 100-101 under 35 USC § 103(a) as being unpatentable over Onishi in view of Rowland et al.

As discussed above, Onishi fails to teach a coating containing heparin dispersed in a polymer as listed in claim 58. Rowland does not cure this omission. Therefore, these combined references do not make claim 58 obvious. Claim 59 depend from claim 58 and is patentable for at least the same reason as claim 58. Claim 48 depends from claim 60 and is patentable for at least the same reason as claim 60.

Tridodecylmethyl ammonium chloride does not contain an aromatic quaternary ammonium ion. If the Examiner believes that it does, she is requested to provide the structure and identify its aromatic portion. Rowland does not mention any benzyl groups let alone benzylalkonium chloride. Therefore, the cited combination fails to teach an "aromatic quaternary ammonium ion" as required by Claim 4. (Applicant points out that its disclosure on page 4, teaches that TDMAC is a large quaternary ammonium ion not that it is an aromatic quaternary ammonium ion.)

Even if the combination were to meet all the limitations of Claim 58, the combination is impermissible. Rowland specifically desires permanent binding of the heparin compound to the medical device substrate. (Rowland, Col. 1, lines 34-37; Col. 3 lines 10-19 and 43-46; and Col. 5, lines 3-9.) According to the Examiner in paragraph 18 of the August 5, 2003, office action, Onishi desires to release heparin compounds into the blood. These references are at cross purposes and teach away from each other. Therefore, Rowland is not combinable with Onishi, and the Examiner has not made out prima facie obviousness.

Rowland is not combinable with Onishi with respect to Claims 100 and 101 either.

Please remove this obviousness-based rejection.

Claims 48 and 59 have limitations in addition to those of their parent claims. Because these claims are patentable for the same reason as their parent claim, Applicant need not explain how the limitations added by the dependent claims further distinguish the claims from these cited teachings. But Applicants do not acquiesce to the Examiner's position with respect to the additional limitations and reserve the right to deal with the specifics of those further limitations in the future, if that becomes necessary.

Paragraph 10

The Examiner has rejected claims 53-57 under 35 USC § 103(a) as being unpatentable over Onishi in view of Rowland et al. and further in view of Hostettler.

As discussed above, Onishi fails to teach a coating containing heparin dispersed in a polymer as listed in claim 58. Rowland does not cure this omission. Therefore, these combined references do not make claim 58 obvious. Claim 59 depends from claim 58 and is patentable for at least the same reason as claim 58. Claim 48 depends from claim 60 and is patentable for at least the same reason as claim 60.

Even if the combination were to meet all the limitations of Claim 53, the combination is impermissible. Rowland specifically desires permanent binding of the heparin

compound to the medical device substrate. (Rowland, Col. 1, lines 34-37; Col. 3 lines 10-19 and 43-46; and Col. 5, lines 3-9.) According to the Examiner in paragraph 18 of the August 5, 2003, office action, Onishi desires to release heparin compounds into the blood. Therefore, Rowland is not combinable with Onishi, and the Examiner has not made out prima facie obviousness.

Please remove this obviousness rejection.

Claims 54-57 have limitations in addition to those of their parent claims. Because these claims are patentable for the same reason as their parent claim, Applicant need not explain how the limitations added by the dependent claims further distinguish the claims from these cited teachings. But Applicants do not acquiesce to the Examiner's position with respect to the additional limitations and reserve the right to deal with the specifics of those further limitations in the future, if that becomes necessary.

Paragraph 11

The Examiner has rejected claims 40-44, 52, 81, and 85-88 under 35 USC § 103(a) as being unpatentable over Onishi in view of Hostettler.

With respect to Claims 40-44 and 52, these claims depend from claim 60 and are therefore patentable for at least the same reasons discussed above for claim 60. With respect to claims 81 and 85-88, these claims have limitation similar to those discussed above for claim 60, and therefore, the discussion for claim 60 applies to these claims, as well. Claims 40-44, 52, and 86-88 have limitations in addition to those of their parent claims. Because these claims are patentable for the same reason as their parent claim, Applicant need not explain how the limitations added by the dependent claims further distinguish the claims from these cited teachings. But Applicants do not acquiesce to the Examiner's position with respect to the additional limitations and reserve the right to deal with the specifics of those further limitations in the future, if that becomes necessary.

Please remove this rejection.

Paragraph 12

Claims 45-47 are rejected under 35 USC § 103(a) as being unpatentable over Onishi in view of Hostettler and further in view of Shah.

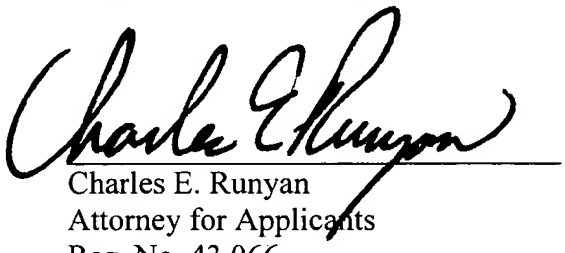
Claims 45-47 depend from claim 60 and are therefore patentable for at least the same reasons discussed above for claim 60.

Please remove this rejection.

Claims 46 and 47 have limitations in addition to those of their parent claims. Because these claims are patentable for the same reason as their parent claim, Applicant need not explain how the limitations added by the dependent claims further distinguish the claims from these cited teachings. But Applicants do not acquiesce to the Examiner's position with respect to the additional limitations and reserve the right to deal with the specifics of those further limitations in the future, if that becomes necessary.

Since all claims are in a condition for allowance, please issue a Notice of Allowability so stating. If I can be of any help, please contact me.

Respectfully submitted,



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